PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Arun Srivastava	**Art Unit:**	1635
Application No.:	10/620,039	**Examiner:**	Whiteman, Brian A.
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For:	VECTOR FOR GENE THERAPY	**Confirmation No.:**	8203

Commissioner for Patents
United States Patent and Trademark Office
Alexandria, Virginia 22313-1450

DECLARATION IN SUPPORT OF REISSUE UNDER 37 C.F.R. §§ 1.175 and 1.63

Sir:

I, Arun Srivastava, declare and state as follows:

1. I am a U.S. citizen and currently reside at 3823 SW 92nd Drive, Gainesville, FL 32608.

2. I believe that I am the original, first and sole inventor of the subject matter which is described and claimed in U.S. Patent No. 6,261,834 ("'834 patent"), granted on July 17, 2001, and for which I solicit a reissue patent.

3. The '834 patent is assigned to Research Corporation Technologies, Inc., Tucson, AZ. As in the '834 patent, the instant reissue application claims priority from International Application PCT/US92/09769, filed on November 6, 1992.

5. I believe that the '834 patent is partly inoperative or invalid by reason of claiming less than there was a right to claim in one aspect and claiming more than there was a right to claim in another aspect.

6. Independent claim 1 is directed to an expression vector. The structural features of the expression vector are set forth in claim 1 as comprising "two inverted terminal repeats of adeno-associated virus 2 and at least one cassette comprising a promoter capable of effecting cell-specific expression wherein said promoter is operably linked to a heterologous gene, and wherein said cassette resides between said inverted terminal repeats." The expression vector is characterized in the preamble as "for site-specific integration and cell-specific gene expression".

7. I believe that the invention of claim 1 of the '834 patent is properly implemented without the preamble expression "for site-specific integration and cell-specific gene expression." A principal feature provided by the '834 patent resides in the recognition that cell-specific expression of a heterologous gene can be achieved by placing such gene under control of a cell-specific promoter and between two ITR sequences of AAV. The AAV ITR sequences achieve stable integration into the host genome without causing substantial toxicity to the host cells, in contrast to the random integration of retroviral vectors. The critical structural elements of the expression vector, i.e., a cell-specific promoter, a heterologous gene and two AAV ITR repeats, are already set forth in claim 1. The preamble "for site-specific integration and cell-specific gene expression" merely describes certain mechanistic features of the recombinant AAV vector and is not necessary for the purpose of defining the expression vector. It is unclear as to whether such mechanistic features in the preamble should be read as a limitation of the expression vector of claim 1. To the extent that such mechanistic features

will be read as a limitation of the expression vector of claim 1, I believe that claim 1 is too narrow and the patent claimed less than there was a right to claim in the patent.

8. This error of claiming less than there was a right to claim in the patent to the extent that the preamble expression is read as a limitation of the claimed expression vector, arose without any deceptive intention on my part.

9. To correct this error and to claim what the patentee had a right to claim, claims 1-15 are canceled and new claims 16-30 are added in the instant reissue application. Claim 16, directed to an expression vector, does not contain the expression "for site-specific integration and cell-specific gene expression." Claims 17-30, which depend from claim 16, are written in the same manner as dependent claims 2-15 of the '834 patent.

10. During prosecution of the instant reissue application, it has come to my attention that U. S. Patent 5,436,146 has issued to Shenk et al. ("Shenk"). Shenk teaches a recombinant AAV vector containing terminal AAV sequences and a foreign DNA sequence operably linked to a promoter. Shenk discloses the use of 191 bp segments from the termini of psub201, a vector which contains AAV-2 DNA. Further, Shenk discloses, in the form of a laundry list, tissue specific promoters that can be employed in the recombinant AAV vector, although Shenk does not provide any showing of tissue specific expression of a heterologous gene from the recombinant AAV vector.

11. To the extent that the expression vector of the '834 patent is considered to be anticipated by Shenk, I believe that the '834 patent is partly inoperative or invalid by reason of claiming more than there was a right to claim.

12. This error of claiming more than there was a right to claim in the patent to the extent that the expression vector is considered to be anticipated by Shenk, arose without any deceptive intention on my part.

13. To correct this error and to claim what the patentee had a right to claim, claim 16 is written to recite "wherein each of said inverted terminal repeats is SEQ ID NO: 1 or a fragment of SEQ ID NO: 1 that comprises nucleotides 1 to 125 of SEQ ID NO: 1." Support for such recitation is found in the specification, e.g., on col. 9, lines 41-45. Shenk does not teach a recombinant AAV-2 vector, as characterized in claims 16-30.

14. All errors in the '834 patent, which I seek to correct by the instant reissue application, arose without any deceptive intention on my part.

15. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with 37 C.F.R. § 1.56.

16. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: May 4, 2005

Srivastava

Arun Srivastava